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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,319	SHORT ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/1/06

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,11-17,20-22 and 50-62* is/are pending in the application.

4a) Of the above claim(s) *3,6 and 11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,20-22 and 51-62* is/are rejected.

7)☒ Claim(s) *50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/29/03; 2/23/04; 9/16/04; 6/20/05; 2/28/06; 4/24/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-3, 6, 11-17, 20-22, 50-62 are pending.

Applicant's amendment of claims 1-3, 11, 13, cancellation of claims 4-5, 7-10, 18-19, 23-49, and addition of claims 51-62 in a communication filed on 5/1/2006 is acknowledged.

Applicant's election with traverse of Group IV, claims 1-2, 20-22, 29, 50 drawn in part to a method to recombinantly produce the polypeptide of SEQ ID NO: 10, as submitted in a communication filed on 5/1/2006 is acknowledged.

Applicant's traverse is on the ground(s) that all claims encompassing exemplary phytases should be rejoined. Specifically, Groups III-IV should be rejoined to a generic group drawn to methods for making a polypeptide having phytase activity wherein said polypeptide is produced in a yeast cell. Applicant asserts that if the instant group restriction requirement is allowed to stand, Applicant will not be able allowed to claim their invention as they choose and the full scope of claims 1-2 would never be examined. Applicant cite case law and refers to 37 CFR 1.146 and MPEP 809.02(a) in support of the argument that while the Examiner can request from Applicant an election of a species of his/her invention, the generic claims are still subject to examination. Applicant request that the restriction requirement with respect to all SEQ ID NO:s be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a).

Applicant's arguments have been fully considered. The Examiner acknowledges that claims 1-2 are generic claims linking patentable distinct inventions and that Applicant is entitled to examination of these generic claims. While not specifically stated in the restriction requirement as such, the Examiner included generic claims 1-2 in both Groups III and IV. Clearly, an election of either Group III or IV would require examination of generic claims 1-2. Thus, contrary to Applicant's assertions, the Examiner is not denying Applicant the examination of the full scope of their invention as set forth in claims 1-2.

Arguments indicating that the restriction requirement should be withdrawn and treated instead as an election species are not found persuasive. Claims 1-2 link two properly divisible inventions as set forth in MPEP 809.03 for the reasons of record. Therefore, a restriction requirement is proper so long as the linking claim(s) are found non allowable. Claims 1-2 and new claim 51 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-2 and new claim 51. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The requirement is still deemed proper and therefore is made FINAL.

Claims 1-2 are not allowable at this time. Claims 3, 6, 11-17 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. New claims 51, 53-62 are generic claims. Claims 50 and 52 are directed in part to the elected subject matter and will examined to the extent it encompasses the elected invention (i.e., a method to recombinantly produce the

polypeptide of SEQ ID NO: 10). Claims 1-2, 20-22, 51, 53-62 and claims 50, 52 in part are at issue and are being examined herein.

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 27, line 26. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Priority

2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/866,379 filed on 05/24/2001, 09/580,515 filed on 05/25/2000, 09/318,528 filed on 05/25/1999, 09/291,931 filed on 04/13/1999, 09/259,214 filed on 03/01/1999, and 08/910,798 filed on 08/13/1997.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 7/29/2003, 2/23/2004, 9/16/2004, 6/20/2005, 2/28/2006, 4/24/2006 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

4. The drawings submitted 6/20/2003 have been reviewed and are accepted by the Examiner.

Claim Objections

5. Claim 52 is objected to due to the recitation of "phytase-encoding nucleic acid nucleic acid". Appropriate correction is required.

6. Claims 54 and 56 are objected to due to the recitation of "signal sequence signal peptide". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 20-21, 51-56, 59-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 20 is indefinite in the recitation of "wherein the nucleic acid further comprises a cloning vehicle" for the following reasons. As known in the art, a polypeptide-encoding nucleic acid is usually inserted in a cloning vehicle. As such, it is the cloning vehicle that comprises the nucleic acid. For examination purposes, it will be assumed that the term reads "wherein the nucleic acid is contained in a cloning vehicle". Correction is required.

10. Claim 21 is indefinite in the recitation of "wherein the cloning vehicle comprises an expression cassette, a vector...." for the following reasons. As written, it is unclear if (a) the intended meaning of the term "comprises" is that of "is", (b) the cloning vehicle physically contains what is recited immediately after the term, since the term "comprises" can be understood as "has", or (c) the cloning vehicle can be anything else in addition to what is being recited immediately after due to the fact that the term "comprises" is considered open language. It is also noted that the term "cloning vehicle comprises an expression cassette" is unclear and confusing. The term "cloning vehicle" as understood in the art

implies that the vehicle is a nucleic acid which would allow cloning but not necessarily expression. In general, the art differentiates cloning from expression. This is evidenced by the fact that there are commercially available vectors which are specifically labeled for either cloning or expression as each vector would contain elements specific for a particular function. In general, one of skill in the art would not use an expression vector for cloning. Therefore, it is unclear as to how a cloning vehicle would contain an expression cassette or be an expression cassette. Furthermore, the term "cloning vehicle comprises a phage/bacteriophage/artificial chromosome/cosmids" is confusing because in general phages, bacteriophages, cosmids and artificial chromosomes are already very large nucleic acids. Therefore, it is unclear as to what else could be included in a cloning vehicle comprising these very large nucleic acids. For examination purposes, no patentable weight will be given to the term "expression cassette", and it will be assumed that the claim reads "wherein the cloning vehicle is a vector....". Correction is required.

11. Claims 51-53, 55 (claims 54, 56, 59-62 dependent thereon) are indefinite in the recitation of "sequence initially derived from a bacterium" for the following reasons. In its broadest reasonable interpretation, the term "derived" encompasses not only sequences which are isolated from a particular source but it also encompasses any variant thereof. Therefore, it is unclear as to which variant sequences are encompassed by the term "sequence initially derived" since the term "derived" alone already encompasses all variants of such sequence. It is also noted that variants derived from a particular sequence would also encompass non-natural sequences. For examination purposes, no patentable weight will be given to the term "initially".

12. Claim 52 is indefinite in the recitation of "the method of claim 51 wherein the phytase-encoding nucleic acid ..has a sequence as set forth in SEQ ID NO: 9...., and the sequence initially derived from a bacterium comprises..." for the following reasons. The term "sequence initially derived from a bacterium" as recited in claim 51, from which claim 52 depends, refers to a limitation for the entire genus of nucleic acids encoding the phytase. The term "and the sequence derived from a bacterium comprises"

as recited in claim 52 implies that there are two nucleic acid sequences being referred to in claim 51. However, claim 51 does not refer to two nucleic acid sequences as it is generic with regard to the phytase-encoding nucleic acid. For examination purposes, claim 52 will be interpreted as being directed to the method of claim 51 wherein the phytase-encoding nucleic acid comprises a sequence as set forth in SEQ ID NO: 9 or encodes an amino acid sequence as set forth in SEQ ID NO: 10. Correction is required.

13. Claims 54 and 56 are indefinite in the recitation of "wherein the homologous signal sequence or the heterologous signal sequence....comprises a secretory signal peptide" for the following reasons. As known in the art, an amino acid sequence is a graphical representation of the order in which amino acids are arranged in a polypeptide. Therefore, it is unclear as to how a sequence can comprise a molecule. For examination purposes, it will be assumed that the term reads "wherein the homologous signal sequence or the heterologous signal sequence....encodes a secretory signal peptide". Correction is required.

14. Claim 60 is indefinite in the recitation of "promoter comprises ADH or LEU2 or the inducible promoter comprises GAL" for the following reasons. The terms "ADH" and "GAL" are abbreviations of the terms "alcohol dehydrogenase" and "galactose" whereas the term "LEU2" refers to a gene. While one of skill in the art would know the ADH, LEU2 and GAL promoters, the term "promoter comprises" implies that the promoter encompasses alcohol dehydrogenase (enzyme), galactose (sugar) or the Leu2 gene in view of the fact that the term "comprises" can be interpreted as "has". For examination purposes, it will be assumed that the claim reads "promoter is ADH or LEU2 or the inducible promoter is GAL". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 55-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 55-56 require nucleic acids encoding a phytase, wherein the phytase comprises a signal sequence and further comprises a sequence imparting a desired characteristic. While the specification provides support for nucleic acids encoding phytase fusion proteins and provides support for a nucleic acid encoding a fusion enzyme including an N-terminal identification peptide imparting desired characteristics (page 64, lines 22-27), the Examiner is unable to find support for a nucleic acid encoding a phytase further comprising any sequence imparting a desired characteristic. Thus there is no indication that the instant genus of nucleic acids were within the scope of the invention as conceived by Applicant at the time the application was filed. Accordingly, Applicant is required to cancel the new matter in the response to this Office Action.

17. Claims 1-2, 20-22, 51, 53-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As indicated above, the term "derived from a bacteria" does not limit the genus of phytases to those isolated from bacteria but encompasses any phytase in view of the fact that the term "derived" encompasses any number of modifications. Therefore, claims 1-2, 20-22, 51, 53-62 are directed to a method for the recombinant production of any polypeptide having phytase activity. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In the instant case, the claims recite a structurally diverse genus of polypeptides. While the specification discloses the polypeptide of SEQ ID NO: 10 as a phytase variant of an *E. coli* phytase, the specification fails to disclose (1) the specific amino acid fragments within SEQ ID NO: 10 which are essential for any polypeptide comprising them to display phytase activity, (2) a correlation between structure and phytase activity, or (3) additional phytases.

While a sufficient written description of a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by amino acid sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus, in the instant case, there is no structural feature recited. The genus of polypeptides recited is potentially extremely variable in structure. While one could argue that the disclosure of the polypeptide of SEQ ID NO: 10 and other phytases known in the art provide adequate description for all the members of the genus

of phytases recited, it is noted that the art teaches several examples of how even small variations in structure can lead to functional variation. For example, Witkowski et al. (Biochemistry 38:11643-11650, 1999; cited in the IDS) teaches that mutations which result in one conservative amino acid substitution transform a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminate β-ketoacyl synthase activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001; cited in the IDS) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Therefore, since (a) minor structural variations may result in changes affecting function, (b) there is no additional information correlating structure with phytase activity, (c) there is no teaching or suggestion as to which portions of the polypeptide of SEQ ID NO: 10 are required in any polypeptide such that it would have the same enzymatic activity as that of the polypeptide of SEQ ID NO: 10, and (d) no information has been provided in regard to which amino acids in the polypeptide of SEQ ID NO: 10 can be modified and which ones need to be conserved to avoid loss of activity, one cannot reasonably conclude that the polypeptide of SEQ ID NO: 10 is representative of all the phytases as recited.

Due to the fact that the specification/art only discloses a few species of the recited genus of polypeptides, and the lack of description of any additional species by any relevant, identifying characteristics or properties, one of skill in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention.

18. Claims 1-2, 20-22, 51, 53-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to recombinantly produce the polypeptide of SEQ ID NO: 10, does not reasonably provide enablement for a method to recombinantly produce any phytase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2nd 1400 (Fed. Cir. 1988)) as follows: (1) quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence and absence of working examples, (4) the nature of the invention, (5) the state of prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claims. The factors which have lead the Examiner to conclude that the specification fails to teach how to make and/or use the claimed invention without undue experimentation, are addressed in detail below.

The breath of the claims. Claims 1-2, 20-22, 51, 53-62 are so broad as to encompass a method to recombinantly produce any phytase. See Claim Rejections under 35 USC 112, second paragraph, and 112, first paragraph, written description, for claim interpretation and discussion of scope. The enablement provided is not commensurate in scope with the claims due to the extremely large number of phytases of unknown structure encompassed by the claims. In the instant case, the specification enables a method to recombinantly produce a phytase comprising SEQ ID NO: 10.

The amount of direction or guidance presented and the existence of working examples. The specification discloses the polypeptide of SEQ ID NO: 10 as a phytase variant of an *E. coli* phytase as a working example. However, the specification fails to provide any clue as to (1) a correlation between structure and phytase activity, (2) other phytases in addition to those disclosed in the specification and the prior art, (3) or the structural elements in the polypeptide of SEQ ID NO: 10 essential for phytase activity.

The state of prior art, the relative skill of those in the art, and the predictability or unpredictability of the art. The amino acid sequence of a protein determines the structural and functional properties of that protein. In the instant case, neither the specification nor the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any phytase. In addition, the art does not provide any teaching or guidance as to (1) which amino acids within

SEQ ID NO: 10 are required for phytase activity, (2) which amino acids within SEQ ID NO: 10 can be modified and which ones can be conserved such that variants of the polypeptide of SEQ ID NO: 10 would display the same phytase activity of the polypeptide of SEQ ID NO: 10, or (3) the general tolerance of phytases to structural modifications and the extent of such tolerance.

The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (Introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991; cited in the IDS) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by experiments where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing *de novo* stable proteins with specific functions. The teachings of Branden et al. are further supported by the teachings of Witkowski et al. and Seffernick et al. already discussed above, where it is shown that even small amino acid variations result in enzymatic activity changes.

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification. While methods of generating or isolating variants of a polypeptide were known in the art at the time of the invention, it was not routine in the art to screen by a trial and error process for all the polypeptides having phytase activity. In the absence of (1) a rational and predictable scheme for modifying any amino acid in the polypeptide of SEQ ID NO: 10 such that the resulting variant would have the same enzymatic activity as that of the polypeptide of SEQ ID NO: 10, and/or (2) a correlation between structure and phytase activity, one of skill in the art would have to assay an extremely large number of polypeptides to find those having phytase activity.

While current screening techniques in the art would allow for testing a limited number of species, testing an unlimited number of polypeptides to determine which ones have phytase activity would not be possible. Therefore, while enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims.

Therefore, taking into consideration the extremely broad scope of the claims, the lack of guidance, the amount of information provided, the lack of knowledge about a correlation between structure and function, the high degree of unpredictability of the prior art in regard to structural changes and their effect on function, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to practice the claimed invention. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claims 1-2, 20-22, 51, 53-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Berka et al. (U.S. Patent No. 5866118, issued 2/2/1999, filed 3/18/1997).

Claims 1-2, 20-22, 51, 53-62 of the instant application are directed in part to a method for recombinantly producing any phytase in a yeast cell, wherein said method requires transforming the yeast cell with a vector comprising a nucleic acid encoding the phytase, wherein said nucleic acid is operatively linked to a promoter, wherein said vector is an expression vector, a plasmid, a phage, a phagemid, a cosmid, a fosmid, a bacteriophage, or an artificial chromosome, wherein said promoter is inducible or constitutive, wherein said inducible promoter is a GAL promoter, wherein said constitutive promoter is an ADH or LEU2 promoter, wherein said yeast cell is *S. cerevisiae, S. pombe, S. occidentalis, P. pastoris or H. polymorpha*, wherein said phytase comprises a signal peptide which is either homologous or heterologous, and wherein said phytase is secreted by the yeast cell. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation.

Berka et al. teach cloning and recombinant production of a *Thermomyces lanuginosus* phytase (Figures 1 & 2). Berka et al. teach the recombinant production of the phytase in *S. cerevisiae* (column 17, lines 10-21) transformed with expression vectors (column 13, lines 62-31) which contain ADH and GAL yeast promoters (column 13, lines 49-50). Berka et al. also teach the use of signal peptides for secretion of the phytase (column 12, lines 1-48) and the use of small extensions to the phytase to aid in purification such as polyhistidine tags, antigenic epitopes, and binding domains (column 3, line 66-column 4, line 3). Therefore, the method of Berka et al. anticipate the instant claims as written.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-2, 20-22, 51, 53-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 5876997. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-2, 20-22, 51, 53-62 of the instant application are directed in part to a method for recombinantly producing any phytase in a yeast cell, wherein said method requires transforming the yeast cell with a vector comprising a nucleic acid encoding the phytase, wherein said nucleic acid is operatively linked to a promoter, wherein said vector is an expression vector, a plasmid, a phage, a phagemid, a cosmid, a fosmid, a bacteriophage, or an artificial chromosome, wherein said promoter is inducible or constitutive, wherein said inducible promoter is a GAL promoter, wherein said constitutive promoter is an ADH or LEU2 promoter, wherein said yeast cell is *S. cerevisiae, S. pombe, S. occidentalis, P. pastoris or H. polymorpha*, wherein said phytase comprises a signal peptide which is either homologous or heterologous, and wherein said phytase is secreted by the yeast cell. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation.

Claim 9 of U.S. Patent No. 5876997 is directed to a method for recombinantly producing a phytase in a host cell transformed with an expression vector comprising a nucleic acid encoding a phytase (SEQ ID NO: 2 in U.S. Patent No. 5876997). The nucleic acid in the method of claim 9 would have to be operatively linked to a promoter as it is in an expression vector. The specification of U.S. Patent No. 5876997 discloses as a preferred embodiment the recombinant production of the phytase in yeast cells (column 12, lines 3-5), including *S. cerevisiae* (column 13, lines 4-7), transformed with a variety of vectors such as expression vectors, plasmids, phages, etc. (column 11, lines 19-30; column 11, lines 35-42), wherein the phytase can be secreted from the host cell by using a signal peptide (leader sequence;

column 9, lines 56-66). The phytase of U.S. Patent No. 5876997 comprises a homologous signal sequence. The embodiment disclosed in U.S. Patent No. 5876997 provides support for the method of claim 9 of U.S. Patent No. 5876997. Therefore, the invention of claims 1-2, 20-22, 51, 53-62 of the instant application are deemed an obvious variation of the invention of claim 9 of U.S. Patent No. 5876997.

23. Claims 1-2, 20-22, 51, 53-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6190897. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-2, 20-22, 51, 53-62 of the instant application are directed in part to a method for recombinantly producing any phytase in a yeast cell, wherein said method requires transforming the yeast cell with a vector comprising a nucleic acid encoding the phytase, wherein said nucleic acid is operatively linked to a promoter, wherein said vector is an expression vector, a plasmid, a phage, a phagemid, a cosmid, a fosmid, a bacteriophage, or an artificial chromosome, wherein said promoter is inducible or constitutive, wherein said inducible promoter is a GAL promoter, wherein said constitutive promoter is an ADH or LEU2 promoter, wherein said yeast cell is *S. cerevisiae, S. pombe, S. occidentalis, P. pastoris or H. polymorpha*, wherein said phytase comprises a signal peptide which is either homologous or heterologous, and wherein said phytase is secreted by the yeast cell. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation.

Claim 9 of U.S. Patent No. 6190897 is directed to a method for recombinantly producing a phytase in a host cell transformed with an expression vector comprising a nucleic acid encoding a phytase (SEQ ID NO: 2 in U.S. Patent No. 6190897). The nucleic acid in the method of claim 9 would have to be operatively linked to a promoter as it is in an expression vector. The specification of U.S. Patent No. 6190897 discloses as a preferred embodiment the recombinant production of the phytase in yeast cells

(column 12, lines 9-10), including *S. cerevisiae* (column 13, lines 10-13), transformed with a variety of vectors such as expression vectors, plasmids, phages, etc. (column 11, lines 25-36; column 11, lines 41-48), wherein the phytase can be secreted from the host cell by using a signal peptide (leader sequence; column 9, line 62-column 10, line 5). The phytase of U.S. Patent No. 6190897 comprises a homologous signal sequence. The embodiment disclosed in U.S. Patent No. 6190897 provides support for the method of claim 9 of U.S. Patent No. 6190897. Therefore, the invention of claims 1-2, 20-22, 51, 53-62 of the instant application are deemed an obvious variation of the invention of claim 9 of U.S. Patent No. 6190897.

24. Claims 1-2, 20-22, 51, 53-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 28-29, 46, 81, 89-91, 94-96 of copending Application No. 09/777566. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-2, 20-22, 51, 53-62 of the instant application are directed in part to a method for recombinantly producing any phytase in a yeast cell, wherein said method requires transforming the yeast cell with a vector comprising a nucleic acid encoding the phytase, wherein said nucleic acid is operatively linked to a promoter, wherein said vector is an expression vector, a plasmid, a phage, a phagemid, a cosmid, a fosmid, a bacteriophage, or an artificial chromosome, wherein said promoter is inducible or constitutive, wherein said inducible promoter is a GAL promoter, wherein said constitutive promoter is an ADH or LEU2 promoter, wherein said yeast cell is *S. cerevisiae, S. pombe, S. occidentalis, P. pastoris or H. polymorpha*, wherein said phytase comprises a signal peptide which is either homologous or heterologous, and wherein said phytase is secreted by the yeast cell. See Claim Rejections under 35 USC 112, second paragraph for claim interpretation.

Claims 13, 28-29, 46, 81, 89-91, 94-96 of copending Application No. 09/777566 are directed in part to a method for recombinantly producing a phytase in a host cell comprising a nucleic acid encoding a phytase (SEQ ID NO: 2 in copending application No. 09/777566), wherein said nucleic acid is operatively linked to a promoter, wherein said phytase further comprises a homologous or heterologous signal peptide, wherein the host cell glycosylates the phytase, and wherein said host cell is a yeast cell. The specification of copending Application No. 09/777566 discloses as a preferred embodiment the recombinant production of the phytase in yeast cells (page 38, fourth paragraph; page 39, last paragraph), including *S. cerevisiae* (page 40, last paragraph), transformed with a variety of vectors such as expression vectors, plasmids, phages, etc. (page 36, last line-page 37, line 16), wherein the phytase can be secreted from the host cell by using a signal peptide (page 49, second complete paragraph). The phytase of copending Application No. 09/777566 comprises a homologous signal sequence. The embodiment disclosed in copending Application No. 09/777566 provides support for the method of claims 13, 28-29, 46, 81, 89-91, 94-96 of copending Application No. 09/777566. Therefore, the invention of claims 1-2, 20-22, 51, 53-62 of the instant application are deemed an obvious variation of the invention of claims 13, 28-29, 46, 81, 89-91, 94-96 of copending Application No. 09/777566.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

25. A method to recombinantly produce the polypeptide of SEQ ID NO: 10 appears to be allowable over the prior art of record.

26. Claim 50 is objected to as it depends upon a rejected base claim and is directed to non-elected subject matter.

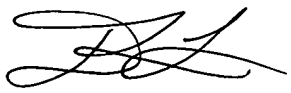
Conclusion

27. No claim is in condition for allowance.

28. The cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



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DR
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